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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,470	10/16/2003	Warren Stern	SOHN-P01-001	8880

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EXAMINER	
STITZEL, DAVID PAUL	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,470	STERN, WARREN	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,8,9 and 11* is/are pending in the application.

4a) Of the above claim(s) *2-4,7,10 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8,9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicant's Response, which was filed on August 2, 2006, in response to the Official Action dated May 11, 2006, is acknowledged.

Status of Claims

Claims 2-4, 7, 10 and 12-17 were withdrawn from further consideration as being directed to non-elected inventions, species and subspecies, in the aforementioned Official Action. Claims 2-4 and 12-17 were canceled, and claims 1, 5, 6, 8, 9 and 11 were amended, by an amendment that accompanied the aforementioned Response. As a result, claims 1, 5, 6, 8, 9 and 11 are therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. § 102, which form the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 5, 6, 8, 9 and 11 stand rejected under 35 U.S.C. § 102(e) as being anticipated by International Patent Application Publication WO03/097011A1 (hereinafter the Barth '011 publication).

With respect to claims 1, 5, 6, 8, 9 and 11 of the instant application, the Barth '011 publication discloses a method of treating gastroesophageal reflux disease (GERD), Zollinger-Ellison syndrome, gastric acid hypersecretion, sleep disorders, sleep apnea, snoring, nocturnal snorting and gasping, wherein said method comprises: administering a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H+,K+-ATPase), such as lansoprazole (a.k.a., Prevacid) (abstract; page 1, lines 8, 9, 22, 23 and 27; page 3, lines 10-13; page 8, lines 2-15; page 13, lines 20-21; page 19, lines 8-16 and 24-34; page 20, lines 1-7; page 27, lines 32-35; page 28, lines 4-7; claims 11-14 and 18).

2. Claims 1, 5, 6, 8, 9 and 11 stand rejected under 35 U.S.C. §§ 102(a) and (e) as being anticipated by U.S. Patent 6,353,005 (hereinafter the Rubin '005 patent).

With respect to claims 1, 5, 6, 8, 9 and 11 of the instant application, the Rubin '005 patent discloses a method of treating gastroesophageal reflux disease (GERD), Zollinger-Ellison syndrome, and gastric hyperacidity, wherein said method comprises administering a composition comprising a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H+,K+-ATPase), such as lansoprazole (a.k.a., Prevacid) (abstract; column 1, lines 1-30; column 3, lines 19-23, 36-39 and 45-50; column 6, lines 5-16; column 7, lines 1-27 and 50-59; column 8, lines 29-53; column 9, lines 15-29 and 58-67; column 10, lines 1-4; column 11, lines 7-15; column 12, lines 3-25; column 14, lines 37-38; claims 10 and 22). Although the Rubin '005 patent does not explicitly teach that that said method and corresponding composition is useful for treating sleep disorders, sleep apnea and snoring, the method of administering a composition comprising a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H+,K+-ATPase), such as lansoprazole (a.k.a.,

Prevacid), would have inherently treated sleep disorders, sleep apnea and snoring, since said chemical composition comprising lansoprazole and its properties are inseperable.

The "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Powder Co. v. Ireco Inc.*, 51 USPQ 2d 1943, 1947 (Fed. Cir. 1999). Therefore, merely claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); and MPEP § 2112. Furthermore "products of identical chemical composition can not have mutually exclusive properties," since a chemical composition and its properties are inseparable. See *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP § 2112. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP § 2112.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 5, 6, 8, 9 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over International Patent Application Publication WO03/053221A2 (hereinafter the Ieni '221 publication) in view of either Senior BA, Khan M, Schwimmer C, Rosenthal L, Benninger M, "Gastroesophageal Reflux and Obstructive Sleep Apnea," Laryngoscope, Vol. 111, pp. 2144-2146 (December 2001) (hereinafter the Senior publication), or Xiao GH, Wang ZF, Ke MY, and Huang XZ, "The Relationship Between Gastroesophageal Reflux Disease (GERD) and Obstructive Sleep Apnea Syndrome (OSAS) and Effects of Anti-Reflux Therapy," Gastroenterology, Vol. 114, No. 4, Part 2, page 336 [G1373] (1998) (hereinafter the Xiao publication).

With respect to claims 1, 5, 6, 8, 9 and 11 of the instant application, the Ieni '221 publication teaches a method of treating GERD, Zollinger-Ellison syndrome, gastric acid hypersecretion, and apnea, wherein said method comprises: administering a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H+,K+-ATPase), including lansoprazole (a.k.a., Prevacid) and/or omeprazole (a.k.a., Prilosec) (abstract; page 1, lines 7-10 and 28-30; page 2, lines 1-3, 9-13 and 29-32; page 3, lines 1-3 and 20-25; page 4, lines 11-17 and 32; page 5, lines 1-3 and 31-32; page 6, lines 1-3; page 7, lines 15-19; page 8, lines 11-17; page 9, line 32; page 10, lines 1-4; page 15, lines 25-29; page 16, lines 5-20; page 17, lines 29-32; page 18, lines 1-3; claims 1, 2, 7, 8, 13 and 14). The Ieni '221 publication does not explicitly teach that the apneic disorder being treated is sleep apnea in particular and symptomatic snoring, which is associated therewith, as instantly claimed.

However, Senior publication teaches a method of treating GERD and obstructive sleep apnea syndrome (OSAS), wherein said method comprises: administering a therapeutically effective amount of a proton pump inhibitor, namely omeprazole (page 2144, column 1, abstract; page 2144, column 2, lines 7-9; page 2145, column 1, lines 26-27, 36-38, 43-44 and 47-56; page 2145, column 2, lines 1-9 and 55-57; page 2146, column 1, lines 1-2 and 5-7).

However, Xiao publication teaches a method of treating GERD and OSAS, wherein said method comprises: administering a therapeutically effective amount of a proton pump inhibitor, namely omeprazole (page 336, [G1373]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed that the method of treating apnea, as broadly recited, via the administration of a therapeutically effective amount of one or more proton pump inhibitor, including lansoprazole and/or omeprazole, as taught by the Ieni '221 publication, would have also been useful in treating specific types of apnea not explicitly recited within the Ieni '221 publication, such as sleep apnea, and in particular OSAS, as well as symptomatic conditions intrinsically associated therewith, such as snoring, as reasonably suggested by the Senior publication and the Xiao publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to treat GERD and OSAS, as well as symptomatic conditions intrinsically associated therewith, such as snoring, by substituting lansoprazole for omeprazole within the methods taught by the Senior publication and the Xiao publication, since the Ieni '221 publication reasonably suggests the interchangeability of lansoprazole and omeprazole for treating GERD and apneic disorders. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in utilizing lansoprazole in place of omeprazole for the treatment of GERD and OSAS, as well as symptomatic conditions intrinsically associated therewith, such as snoring, since both the Senior

publication and the Xiao publication teach administering a proton pump inhibitor, namely omeprazole, for the treatment of GERD and OSAS, and the Ieni '221 publication reasonably suggests the interchangeability of lansoprazole and omeprazole for treating GERD and apneic disorders.

Although none of the aforementioned prior art references explicitly teach a method of treating snoring, per se, the Ieni '221 publication teaches a method of treating apneic disorders, the Senior publication teaches a method of treating obstructive sleep apnea syndrome (OSAS), and the Xiao publication teaches a method of treating OSAS. Because snoring is a symptomatic condition intrinsically associated with OSAS, administration of a therapeutically effective amount of a proton pump inhibitor, such as lansoprazole and omeprazole, would intrinsically treat not only OSAS, but also symptomatic conditions intrinsically associated therewith, such as snoring, as instantly claimed.

Examiner's Response to Applicant's Remarks

Although Applicant's arguments as set forth in the aforementioned Response have been fully considered in light of the claims as currently amended, they are not persuasive. Applicant's claim amendments necessitated the new grounds of rejection as set forth hereinabove.

1. 35 U.S.C. § 102(e) rejection of claims 1, 5, 6, 8, 9 and 11 based on the Barth '011 publication.

Applicant argues on pages 4 and 5 of the aforementioned Response that the entire specification of the Barth '011 publication only mentions treating snoring once and as a result the instantly amended claims are not anticipated. In response to Applicant's arguments, there is no *de minimis* requirement as to how many times a reference must explicitly state a claim limitation before said reference becomes an anticipatory piece of prior art. All that is required is that the instantly claimed invention would have been rendered anticipated and/or obvious to one of ordinary skill in the art at the time the instant application was filed in light of the disclosure and/or teachings of the prior art reference.

Applicant also argues in the last paragraph on page 4 of the aforementioned Response that the Barth '011 publication teaches that sleep apnea can be treated using proton pump inhibitors (i.e., inhibitors of H+,K+-ATPase), such as lansoprazole (a.k.a., Prevacid), and that by treating sleep apnea, symptomatic conditions intrinsically associated therewith (i.e., snoring) are likewise alleviated. The Examiner of record is in agreement with this assertion.

2. 35 U.S.C. §§ 102(a) and (e) rejection of claims 1, 5, 6, 8, 9 and 11 based on the Rubin '005 patent.

Applicant argues on pages 5 and 6 of the aforementioned Response that simply because the Rubin '005 patent discloses a method of treating patients suffering from GERD, only *some* of which would also suffer from snoring, by administering a proton pump inhibitor (i.e., lansopraxole), does not necessarily mean that the Rubin '005 patent also inherently discloses the use of said lansopraxole proton pump inhibitor for treating snoring. In response to Applicant's arguments, the Applicant does not recite a method of treating snoring comprising administering a lansopraxole proton pump inhibitor to a patient "in need thereof." As a result, the patient population is not narrowly defined within said claim and thus may include patients suffering from GERD and/or snoring. Amending claim 1 to recite a method of treating snoring comprising administering a lansopraxole proton pump inhibitor to a patient "in need thereof," would overcome the instant 35 U.S.C. §§ 102(a) and (e) rejection of claims 1, 5, 6, 8, 9 and 11 based on the Rubin '005 patent.

Applicant also argues on pages 5 and 6 of the aforementioned Response that Applicant is claiming a new method of using an old composition, not the old composition itself, and as such the holding of *In re Best* is in not applicable. In response to Applicant's arguments, MPEP § 2112

explicitly states that the holding of *In re Best* is equally applicable to process claims that are claimed in terms of function, properties or characteristics.

Applicant also asserts on pages 5 and 6 of the aforementioned Response that Applicant disagrees with the Examiner's assertion that because the properties of a lansopraxole proton pump inhibitor are inseparable therefrom, one would inherently treat snoring upon the administration of said lansopraxole proton pump inhibitor to a patient suffering from GERD. If such an assertion were true, which it is not, then the instant method claims would therefore necessarily be non-enabled for treating snoring via the administration of said lansopraxole proton pump inhibitor under 35 U.S.C. § 112, first paragraph.

3. 35 U.S.C. § 103(a) rejection of claims 1, 5, 6, 8, 9 and 11 based on the Ieni '221 publication in view of either the Senior publication, or the Xiao publication.

Applicants argue on pages 6 and 7 of the aforementioned Response that none of the prior art references explicitly teach a method of treating snoring and thus a prima facie case of obviousness has not been met. In response to Applicant's arguments, although none of the aforementioned prior art references explicitly teach a method of treating snoring, per se, the Ieni '221 publication teaches a method of treating apneic disorders, the Senior publication teaches a method of treating obstructive sleep apnea syndrome (OSAS), and the Xiao publication teaches a method of treating OSAS. Because snoring is a symptomatic condition intrinsically associated with OSAS, administration of a therapeutically effective amount of a proton pump inhibitor, such as lansoprazole and omeprazole, would intrinsically treat not only OSAS, but also symptomatic conditions intrinsically associated therewith, such as snoring, as instantly claimed.

Conclusion

Applicant's claim amendments necessitated the new grounds of rejection presented in this Official Action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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